

## REMARKS

### Status of the Claims

Claims 6, 7, 9-43, 49-59, 61, and 62 are pending. Claims 22-43, and 49-54 are withdrawn. Claims 6 and 13 are amended above.

### Examiner Interview Summary

A telephonic interview was conducted on August 19, 2008, between Examiner Pak and Applicants' representative. During the interview, the pending claims were discussed as well as the cited prior art. Additionally, amendments were proposed that Applicants submitted would overcome the rejections of record. The time and attention of the Examiner during the interview are greatly appreciated.

### Claim Objections

Claim 6 was objected to for minor informalities. In view of the amendment, this objection is moot. The phrase "living mammalian" was amended to recite "living mammal".

Accordingly, Applicants respectfully submit that this objection should be withdrawn.

### Issues Under 35 U.S.C. § 112

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. This rejection is respectfully traversed. However, in view of the above amendment that cancels claim 4, this rejection is moot.

Issues Under 35 U.S.C. § 102

Claim 4 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the Yu et al. reference. This rejection is respectfully traversed. However, in view of the above amendment that cancels claim 4, this rejection is moot.

Issues Under 35 U.S.C. § 103

Claims 6-7, 9-21, and 55-62 are rejected under 35 U.S.C. § 103 as allegedly being obvious over Yu et al. in view of Taketo.<sup>1</sup> This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Both of these references and their deficiencies with respect to the current claims are well-discussed in the record.

In general, the Office Action states that Yu et al. disclose “detecting/measuring COX-2 in a sample by detecting/measuring a PEGH<sub>2</sub>-EA metabolite [sic]...[and] generating a standard value and curve for detecting COX-2 activity.” Additionally, the Taketo article is relied on for the notion that “COX-2 expression is increased in cancerous cells.”

In responding to Applicants’ previous arguments, the current Office Action rests, in part, on a distinction between “mammalian cell” and “living subject.” The Office Action, at page 8, states that “[the] Examiner respectfully disagrees. A ‘mammalian cell’ is a ‘living subject’.”

In view of the above amendment, it should be clear that the present claims relate to a living mammal, and not a cell (as in the Yu et al. reference). In view of this amendment alone, it is clear that Yu et al. should be withdrawn as a primary reference.

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<sup>1</sup> The Office Action indicates that the secondary reference is Tsujii. However, it is clear from the rejection that “Taketo” is intended.

As stated in the previous response, Yu et al. grow cultured cells, then induce COX-2 on order to determine if the cultured cells metabolize COX-2. This is a clear distinction between taking a sample from a living subject and using that sample to determine COX-2 activity in the subject. The distinction should be even more clear by the fact that Yu et al. did not even see a purpose for the metabolism of AEA by COX-2.<sup>2</sup>

The Office Action additionally summarized one of the points raised in the previous response as follows: "Applicants also point out that Yu et al. grow cultured cells and then induce COX-2 and then determine if the cultured cells metabolize COX-2. It is not clear what applicants are arguing."

Applicants respectfully submit that this point further exposes the difference between Yu et al. and the preset invention, and why one of ordinary skill in the art would not look to Yu et al. as a means of arriving at the present invention. In a way, Yu et al. are heading the opposite direction as the present invention. Instead of taking a sample and then determining the present of COX-2 activity, Yu et al. perform the opposite steps. Yu et al. first start with COX-2 induction of cultured cells, and then determine if the induced COX-2 activity metabolizes AA and AEA. This measurement cannot be equated with the present claims. "Metabolism of AEA by COX-2 [that was induced in a cultured cell sample]" cannot be equated with relating the detected amount of a PGH<sub>2</sub>-EA metabolite in a sample with the progression of a disease state, for example.

Further, in connection with the relating step, Applicant respectfully submits that the references cannot be combined as suggested because there is nothing in the references associated with detecting an amount of a PGH<sub>2</sub>-EA metabolite in the sample of a mammal. Again, COX-2

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<sup>2</sup> "At the present time the physiological significance of the metabolism of AEA by COX-2 is not known." See Yu et al. at page 21186.

was first induced by Yu et al. Beginning with the induction of COX-2 in cultured cells does not permit one of ordinary skill in the art to "relate the amount of PGH<sub>2</sub>-EA metabolites... to [a] disease state" as alleged on page 7 of the Office Action.

Additionally, the Office Action maintains that Yu et al. disclose "generating a standard value and curve for determining COX-2 activity [citing Figure 1 and Table 1]." See page 7 of the Office Action. Applicants respectfully submit that such reliance is misplaced, and fails to address the entire scope of the claim. Applicant respectfully submits that data show, *inter alia*, binding site competition between AA and AEA. This information is not relevant to the claimed "comparing", "relating", "associating", etc. steps. One reason is because there is no indication that measurement of the competitive metabolism of AA or AEA is related to the claimed uses of the metabolites.

Thus, Applicants submit that the above claims are free from the above rejection.

From the foregoing, further and favorable reconsideration in the form of a Notice of Allowance is requested and such action is believed to be in order.

If the Examiner has any questions concerning this amendment or the application in general, please contact the undersigned at the number listed below.

Respectfully submitted,



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